

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X
JOHN TRISVAN,

Plaintiff,

-against-

TOM HEYMAN, et al.,

Defendants.
-----X

:
:
:
:
:
:
:
:

1:16-cv-00084-MKB-LB

**MEMORANDUM OF LAW IN SUPPORT OF JANSSEN PHARMACEUTICALS, INC.
AND JANSSEN RESEARCH & DEVELOPMENT, LLC'S MOTION TO DISMISS
PLAINTIFF'S SECOND AMENDED COMPLAINT WITH PREJUDICE**

PATTERSON BELKNAP WEBB & TYLER LLP

John D. Winter

Thomas P. Kurland

1133 Avenue of the Americas

New York, NY 10036-6710

T: (212) 336-2000

E: jwinter@pbwt.com

tkurland@pbwt.com

Attorneys for Defendants

*Janssen Pharmaceuticals, Inc. and Janssen
Research & Development LLC*

TABLE OF CONTENTS

TABLE OF AUTHORITIES	ii
PRELIMINARY STATEMENT	1
FACTUAL AND PROCEDURAL SUMMARY	2
LEGAL STANDARD.....	5
ARGUMENT	6
I. PLAINTIFF DOES NOT STATE A CLAIM FOR FAILURE TO WARN	6
A. Plaintiff Makes No Allegations that Risperdal®'s Warnings Were Inadequate and Incorrectly Alleges the Relevant Warnings Were Nonexistent	7
B. The Learned Intermediary Rule Attaches Because Plaintiff Has Alleged that His Psychiatrist Was Aware of Risperdal®'s Side-Effects	8
C. Plaintiff Has Not Alleged that His Risperdal® Use Was Off-Label or that Any of His Purported Side-Effects Are Unique to Off-Label Use	10
II. THE COURT SHOULD DENY PLAINTIFF FURTHER LEAVE TO AMEND.....	12
CONCLUSION.....	13

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Alston v. Caraco Pharm., Inc.</i> , 670 F. Supp. 2d 279 (S.D.N.Y. 2009).....	8
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	6
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	2, 6
<i>Caldwell v. Pesce</i> , 83 F. Supp. 3d 472 (E.D.N.Y. 2015)	5
<i>Coleson v Janssen Pharm., Inc.</i> , 251 F Supp 3d 716 (S.D.N.Y. 2017).....	4
<i>Dauids v. Novartis Pharm. Corp.</i> , 857 F. Supp. 2d 267 (E.D.N.Y. 2012)	8
<i>Delta Air Lines v. Kramarsky</i> , 650 F.2d 1287 (2d Cir. 1981).....	5
<i>Garcia v. Falk</i> , 2015 U.S. Dist. LEXIS 40960 (E.D.N.Y. Mar. 30, 2015)	5
<i>Glucksman v. Halsey Drug Co., Inc.</i> , 160 A.D.2d 305 (1st Dep’t 1990)	8
<i>Harris v. Mills</i> , 572 F.3d 66 (2d Cir. 2009).....	5
<i>Hirsch v. Arthur Andersen & Co.</i> , 72 F.3d 1085 (2d Cir. 1995).....	6, 10
<i>In re Livent, Inc. Noteholders Sec. Litig.</i> , 151 F. Supp. 2d 371 (S.D.N.Y. 2001).....	10
<i>McKethan v. New York State Dep’t of Corr. Servs.</i> , 2012 U.S. Dist. LEXIS 84976 (S.D.N.Y. June 19, 2012).....	13
<i>Payne v. Malemathew</i> , 2011 U.S. Dist. LEXIS 80649 (S.D.N.Y. July 22, 2011)	12

<i>Reed v. Pfizer</i> , 839 F. Supp. 2d 571 (E.D.N.Y. 2012)	4, 8
--	------

<i>Terry v. Inc. Vill. of Patchogue</i> , 826 F.3d 631 (2d Cir. 2016).....	13
---	----

Other Authorities

Fed. R. Civ. P. 12(b)(6).....	1, 5, 13
-------------------------------	----------

N.Y. C.P.L.R. § 214-a.....	9
----------------------------	---

Pursuant to Fed. R. Civ. P. 12(b)(6), Defendants Janssen Pharmaceuticals, Inc. and Janssen Research & Development LLC (together, “Janssen” or the “Janssen Defendants”) submit this memorandum of law in support of their motion to dismiss Plaintiff John Trisvan’s Second Amended Complaint with prejudice.

PRELIMINARY STATEMENT

This is Plaintiff’s third bite at the apple. On April 27, 2018, Plaintiff filed his Second Amended Complaint after the Court twice rejected his earlier attempts to recover for purported injuries he allegedly sustained after taking the prescription antipsychotic medicine Risperdal®, which the Janssen Defendants manufacture. Plaintiff, however, fails to remedy any of the defects that resulted in his earlier pleadings’ dismissal.

Throughout this litigation, which began in November 2015, Plaintiff consistently has maintained that Janssen¹ never warned of side effects associated with Risperdal® from which he allegedly suffers—particularly liver damage. And he has insisted this is true even when presented with contradictory evidence. As Janssen has demonstrated multiple times, Risperdal®’s FDA-approved label has explicitly warned of liver damage since at least 1999.

Plaintiff, however, has chosen to ignore this fact to his own detriment. And he continues to do so in his Second Amended Complaint. Even more, Plaintiff has consistently disregarded the Court’s directives regarding the information he must include in his amended pleading to survive dismissal.

¹ Plaintiff’s Second Amended Complaint again names as defendants the non-entities “Janssen Pharmaceuticals” and “Johnson & Johnson Development Corporation.” (ECF No. 61 at 1-3.) The Court’s March 30, 2018 Order dismissing Plaintiff’s Amended Complaint directed the Clerk of the Court to substitute Janssen Pharmaceuticals, Inc., and Janssen Research & Development, LLC for these non-entities. On May 11, 2018, the Court further ordered that the Court will construe Plaintiff’s remaining allegations against Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC. (*See* May 11, 2018 Dkt. Entry.) Accordingly, this motion is brought on behalf of Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC.

It is now abundantly clear that *no facts* exist which would allow Plaintiff to assert a legally viable claim against the Janssen Defendants. Accordingly, Plaintiff's Second Amended Complaint should be dismissed with prejudice in its entirety.

FACTUAL AND PROCEDURAL SUMMARY

After nearly three years and two opportunities to amend his pleadings, Plaintiff has failed to state viable claims against Janssen. This case began on November 23, 2015, when Plaintiff filed a complaint against, among others, high-ranking Johnson & Johnson executives Joaquin Duato, Alex Gorsky, and Tom Heyman (the "Individual Defendants"). (*See generally* ECF No. 1.) Plaintiff alleged that he suffered liver damage, as well as other side-effects, as a result of taking the prescription medication Risperdal®. (*See id.* at 3.) He sought to recover \$25 million from the Individual Defendants for his alleged injuries. (*Id.* at 5)

On May 6, 2016, the Individual Defendants moved to dismiss the original Complaint after Plaintiff failed to allege any facts sufficient to state a claim against them. (*See* ECF No. 26.) On March 24, 2017, the Court granted that motion, concluding that the original Complaint lacked "any allegations specifying how the [Individual] Defendants engaged in any activity that caused Plaintiff's injuries." (*See* ECF No. 33 at 9.) The Court nevertheless permitted Plaintiff to amend his pleadings and directed him to "plead enough facts to state a claim to relief that is plausible on its face." (ECF No. 33 at 10 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).))

On April 14, 2017, Plaintiff filed an Amended Complaint. (ECF No. 34.) Plaintiff, however, did not follow the Court's instructions. Rather, Plaintiff merely re-alleged the same facts that were insufficient to state a claim against the Individual Defendants, added the Janssen Defendants to the caption, and made additional conclusory allegations that he was harmed after consuming Risperdal®. Notwithstanding these defects, Janssen construed

Plaintiff's Amended Complaint to be seeking recovery for (1) Risperdal®'s alleged failure to warn of Plaintiff's side-effects and (2) Risperdal®'s allegedly defective design. Janssen also understood Plaintiff to be pursuing a fraud claim as well as seeking recovery from the Individual Defendants on veil-piercing and/or alter ego theories of liability.

On May 26, 2017, all defendants again moved to dismiss Plaintiff's Amended Complaint. (ECF No. 48.) And, on March 30, 2018, the Court again granted the defendants' motions to dismiss in their entirety. (ECF No. 60 (the "March 30 Order").) Specifically, the Court dismissed Plaintiff's claims against all defendants in this action *with prejudice*, save for Plaintiff's failure-to-warn claim against Janssen, which was dismissed without prejudice and with leave to re-plead. But the Court provided Plaintiff with clear directives regarding the facts he must allege to survive dismissal of any subsequent complaint.

First, to the extent that Plaintiff seeks to recover on his failure-to-warn claim for his alleged side-effects resulting from his use of Risperdal® (particularly liver damage), the Court instructed Plaintiff to "provide non-conclusory allegations as to why he believes Defendants failed to provide warnings to his physicians" regarding Risperdal®'s side-effects. (*Id.* at 24-25.) Second, to the extent that Plaintiff seeks to recover for injuries associated with any purported "off-label" uses of Risperdal®, the Court instructed Plaintiff to "provide specific allegations explaining the purpose for which he has been prescribed Risperdal, the unique risks associated with his off-label use, and why the warnings provided to his physicians were inadequate." (*Id.* at 28.) Additionally, the Court precluded Plaintiff from adding any additional defendants without its prior approval. (*Id.* at 36 n.26.)

On April 27, 2018, Plaintiff filed his Second Amended Complaint. (ECF No. 61.) The allegations in the Second Amended Complaint completely disregard the Court's directives.

For example, despite the fact that only Janssen remains a defendant in this action, Plaintiff reasserted all of his claims against the Individual Defendants as well as GlaxoSmithKline corporate entities and its individual officers. (*See id.* at 3, 6.) Plaintiff also named two additional defendants in violation of the Court’s March 30 Order (ECF No. 60 at 36 n.26): his physician, Dr. Ray Rebotira, as well as V&A Pharmacy (ECF No. 61 at 1, 3).²

Moreover, Plaintiff’s allegations in the Second Amended Complaint fail to remedy any of the specific pleading defects that the Court—and Janssen—identified numerous times. Plaintiff now alleges that his psychiatrist, Dr. Ray Rebotira, prescribed him Risperdal® in October 2011 to treat symptoms associated with his “depression” and an unspecified “personality disorder.”³ (*Id.* at 4.) And he continues to allege that he suffered from liver damage after consuming Risperdal®. (*Id.* at 4-5, 7.) But even in the face of contradictory evidence, Plaintiff maintains that “no mention of liver damage, cirrhosis or fatty liver disease was ever stated as a side effect and possible consequence behind actively taking Risperdal . . .” (*Id.* at 7.) As Janssen has demonstrated repeatedly, Risperdal®’s labeling has expressly warned of such risks since at least 1999,⁴ and Risperdal®’s labeling was also published in the Physicians’ Desk

² The Court dismissed Dr. Rebotira and V&A Pharmacy in a docket order dated May 11, 2018. (“The Court also dismisses new defendants Ray Rebotira and V&A Pharmacy from the action.”)

³ Janssen notes that generic versions of Risperdal® came to market in 2008, three years before Plaintiff now alleges he was prescribed the medicine. *See* Press Release: “FDA Approves First Generic Risperidone to Treat Psychiatric Conditions,” June 30, 2008, *available at* <https://wayback.archive-it.org/7993/20161024164219/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116916.htm> (last visited May 30, 2018) (For the Court’s convenience, a copy of this website is annexed as **Exhibit A** to the Kurland Decl. submitted herewith.) It is therefore unlikely that Plaintiff’s 2011 prescription was filled with brand-name Risperdal® for which Janssen could be liable at all. *See Coleson v Janssen Pharm., Inc.*, 251 F Supp 3d 716, 722 (S.D.N.Y. 2017) (“Plaintiff’s failure to warn claim must fail because he only alleges a warning defect as to risperidone, over which Defendants had no duty of care.”).

⁴ The Court may take judicial notice of Risperdal®’s FDA-approved labels. *See, e.g., Reed v. Pfizer*, 839 F. Supp. 2d 571, 576 (E.D.N.Y. 2012) (taking judicial notice of FDA-approved drug label and granting motion to dismiss). Risperdal®’s FDA-approved label from 1999 (the “1999 Label”) is available at http://www.accessdata.fda.gov/drugsatfda_docs/label/1999/20588s051bl.pdf (last visited May 30, 2018).

Reference, a widely-available source of pharmaceutical labeling information.⁵ Furthermore, Risperdal®’s September 24, 2011 label, which was approved by the FDA shortly before Plaintiff was allegedly prescribed Risperdal in October 2011, continued to warn of these risks.⁶ Plaintiff appears to have reviewed Risperdal®’s FDA-approved labeling exactly zero times after nearly three years of litigation.

Plaintiff’s repeated failure to heed the Court’s instructions merits this action’s dismissal. And his inability—or refusal—to address the deficiencies with his pleadings establishes that any further amendments would be futile.

LEGAL STANDARD

Although courts faced with Rule 12(b)(6) motions should construe the allegations in a light most favorable to the plaintiff, they “need not assume the truth of conclusions of law or unwarranted factual inferences.” *Delta Air Lines v. Kramarsky*, 650 F.2d 1287, 1298 (2d Cir. 1981). While the Court is “obligated to construe a *pro se* complaint liberally,” *Harris v. Mills*, 572 F.3d 66, 72 (2d Cir. 2009), “the liberal pleading standard accorded to *pro se* litigants is not without limits, and all normal rules of pleading are not absolutely suspended.” *Garcia v. Falk*, 2015 U.S. Dist. LEXIS 40960, at *10 (E.D.N.Y. Mar. 30, 2015) (internal quotations and citation omitted). Even “a [*pro se*] complaint must plead sufficient facts to ‘state a claim to relief that is *plausible* on its face.’” *Caldwell v. Pesce*, 83 F. Supp. 3d 472, 480 (E.D.N.Y. 2015), *aff’d*, 639

For the Court’s convenience, a copy of the 1999 Label is annexed as **Exhibit B** to the Kurland Decl. submitted herewith.

⁵ For the Court’s convenience, an excerpt of Risperdal®’s labeling from the 2001 Physicians’ Desk Reference (the “2001 PDR”) is annexed as **Exhibit C** to the Kurland Decl. submitted herewith.

⁶ The September 24, 2011 Label (the “2011 Label”) is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020272s060s066,020588s048s054,021444s035s042lbl.pdf (last visited May 30, 2018). For the Court’s convenience, a copy of the 2011 Label is annexed as **Exhibit D** to the Kurland Decl. submitted herewith.

F. App'x 38 (2d Cir. 2016) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)) (emphasis added). To state a “plausible” claim, a plaintiff must plead “more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court also “may consider all papers and exhibits appended to the complaint, as well as any matters of which judicial notice may be taken.” *Hirsch v. Arthur Andersen & Co.*, 72 F.3d 1085, 1092 (2d Cir. 1995).

ARGUMENT

I. PLAINTIFF DOES NOT STATE A CLAIM FOR FAILURE TO WARN

Although the causes of action Plaintiff is pursuing in the Second Amended Complaint are unclear, Janssen construes Plaintiff to be seeking recovery on the grounds that (1) Janssen did not warn of the side-effects that Plaintiff purportedly suffered after taking Risperdal® (specifically, liver damage), and (2) Janssen did not warn of potential adverse side-effects purportedly associated with “off-label” use of Risperdal®.⁷ Plaintiff, however, cannot recover on either claim. That is because the only injury Plaintiff claims to have sustained is liver damage—a side-effect that has been described in Risperdal®’s FDA-approved labeling since at least 1999. Furthermore, Plaintiff fails to allege that his Risperdal® use was off-label or that his purported liver damage is uniquely associated with off-label usage.

⁷ In the March 30 Order, the Court noted that “Plaintiff may also have causes of action for deceptive conduct under General Business Law section 349 and breach of implied warranty of merchantability.” (ECF No. 60 at 28 n.21.) The Second Amended Complaint does not cite this General Business Law statute nor is there any indication that Plaintiff is pursuing such claims. Instead, Plaintiff makes the vague and conclusory allegation that all defendants in this action—including those that have already been dismissed—engaged in “deceptive tactics in violation of New York’s UCC, along with 12 CFR 202 (5) (i) (iii); (6) (i)(xv); (7) (i) (ii) (vii) (viii); and (3).” (2d Am. Compl., ECF No. 61 at 6.) Here, Janssen understands that Plaintiff is referencing New York’s Uniform Commercial Code and the Code of Federal Regulations. With respect to the UCC, it is unclear what sections Janssen purportedly “violated” and Plaintiff makes no effort to specify which sections are at issue. With respect to the CFR, Plaintiff has cited regulations promulgated by the Board of Governors of the Federal Reserve System that are applicable to creditors, and are of no relevance to any of the allegations in Plaintiff’s Second Amended Complaint.

A. Plaintiff Makes No Allegations that Risperdal®'s Warnings Were Inadequate and Incorrectly Alleges the Relevant Warnings Were Nonexistent

The Court dismissed the Amended Complaint because, among other reasons, Plaintiff's failure-to-warn claims "appear[ed] to be based on his belief that there were *no* warnings about the relevant side-effects" associated with Risperdal®. (ECF No. 60 at 21 (emphasis in original).) As a result, the Court determined that Risperdal®'s "warnings were sufficient based on Plaintiff's argument that *no* warnings were provided to his physicians."⁸ (*Id.* at 22 n.15 (emphasis in original).) Plaintiff repeats this mistake in the Second Amended Complaint. He identifies no deficiencies with Risperdal®'s label (and has opted to ignore the labels entirely). Thus, the issue before the Court is, once again, not whether Risperdal®'s label *adequately* warned of Plaintiff's alleged-side effects. Rather, it is whether the label included *any* warnings whatsoever. (*See id.* at 22.)

Plaintiff continues to rely on the same demonstrably false allegation that resulted in the Court dismissing his prior two Complaints: that Janssen *never* warned that Risperdal® could cause liver damage. (*See* ECF No. 1 at 3; ECF No. 34 at 9, 11.) As Janssen has explained in each of its prior motions to dismiss, Risperdal®'s FDA-approved labeling has explicitly disclosed this side-effect since at least July 2, 1999. More specifically, the 1999 Label disclosed that "liver and biliary system disorders," including "hepatic failure," were observed during Risperdal®'s pre-marketing studies. Ex. B, 1999 Label at 19. The exact same information was also published in the 2001 Physicians' Desk Reference. *See* Ex. C, 2001 PDR at 1583. Furthermore, Risperdal®'s labeling expressly cautioned that "Risperdal doses should be reduced in patients with liver disease" in both the 1999 and 2011 Labels. Ex. B, 1999 Label at 3; Ex. D,

⁸ Janssen notes that the Court did not hold as a matter of law "that the warnings as described were sufficient in all circumstances." (March 30 Order, ECF No. 60 at 22 n.15.)

2011 Label at 46. The Second Amended Complaint does not explain how or why these warnings are inadequate. Moreover, Plaintiff has received the 1999 Label with every round of briefing in this action. (*See* ECF No. 26-6; ECF No. 49-6.) Yet he has chosen to ignore the label at every stage of this litigation. His failure to identify *any* deficiencies with Risperdal®’s label with respect to liver damage—or any side-effect for that matter—cannot be excused.

B. The Learned Intermediary Rule Attaches Because Plaintiff Has Alleged that His Psychiatrist Was Aware of Risperdal®’s Side-Effects

As Janssen argued in its motion to dismiss the Amended Complaint, Plaintiff must allege two things to state a claim for failure to warn: “(1) [Janssen] did not provide his physicians with adequate warnings about risks that it knew or should have known [Risperdal®] to cause; and (2) the inadequacy of those warnings was the proximate cause of his injuries.”

Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009). These requirements flow from New York’s “learned intermediary” rule, which establishes that a

manufacturer of a prescription drug does not have a duty to warn the patient of the dangers involved of the product, but rather the duty is owed to the patient’s doctor. The basis for this rule is that “[t]he doctor acts as an ‘informed intermediary’ between the manufacturer and the patient, evaluating the patient’s needs, assessing the risks and benefits of available drugs, and prescribing and supervising their use.”

Davids v. Novartis Pharm. Corp., 857 F. Supp. 2d 267, 286 (E.D.N.Y. 2012) (internal citations omitted) (quoting *Glucksman v. Halsey Drug Co., Inc.*, 160 A.D.2d 305, 307 (1st Dep’t 1990)). Additionally, “a failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicating how the provided warnings were inadequate.” *Reed*, 839 F. Supp. 2d at 575. As set forth above, Plaintiff has made no allegations regarding the *adequacy* of Risperdal®’s label.

Even more, Plaintiff ignores the Court’s instruction to “provide non-conclusory allegations as to why he believes Defendants failed to provide warnings to his physicians.” (March 30 Order, ECF No. 60 at 25.) In fact, Plaintiff does just the opposite. He alleges not only that his psychiatrist, Dr. Rebotira, was aware of Risperdal®’s side-effects, but also that Dr. Rebotira actively withheld information about Risperdal®. Specifically, Plaintiff alleges that Dr. Rebotira “*refused* to expose the truth about” Risperdal®’s side-effects and that this purported “withholdal [sic] of information led Plaintiff to taking this drug without proper warning.” (2d Am. Compl., ECF No. 61 at 7 (emphasis added).) He further alleges that all of the defendants listed in the Second Amended Complaint—including Dr. Rebotira—“*conspired* with one another to introduce dangerous drugs to the public sector knowingly with no regards to the harm and death that it may cause.” (*Id.* (emphasis added).) To avoid any doubt that Dr. Rebotira knew about the purported side-effects associated with Risperdal®, Plaintiff alleges that “Defendant[] Rebotira . . . being in kahoot [sic], with the drug companies hid the product dangers that came along with consuming the drug, which ultimately led to Plaintiff suffering liver damage.” (*Id.* at 8.) But these allegations do not establish that Janssen failed to provide Dr. Rebotira with information about Risperdal®’s side-effects. Instead, they allege only that Dr. Rebotira purportedly failed to warn Plaintiff.⁹

Although the Court is required to accept a plaintiff’s well-pleaded facts as true, it is not required to suspend disbelief entirely. Yet crediting the Second Amended Complaint’s allegations would require the Court to do just that. And that is because Plaintiff simultaneously

⁹ Janssen notes that even if the Court had not dismissed Dr. Rebotira from this action, Plaintiff could not have asserted a medical malpractice claim against him because it would be untimely. In New York, the limitations period for medical malpractice claims is two years and six months. N.Y. C.P.L.R. § 214-a. Plaintiff alleges that he learned of his alleged liver damage on September 14, 2015. But he did not name Dr. Rebotira as a defendant in this action until April 27, 2018—two years and seven months later (or, more than one month after the limitations period had lapsed).

alleges that Janssen never warned of Risperdal®'s side-effects *and* that his physician somehow knew about the medication's purported side-effects. To harmonize these allegations, the Court must make a series of assumptions—each more implausible than the last. The Court must accept it is true that: (1) Janssen failed to include on Risperdal®'s label *any* warnings about Plaintiff's complained-of side-effects even in the face of contradictory evidence; (2) Janssen purposely hid this information notwithstanding its publication in the PDR; (3) Dr. Rebotira nonetheless learned of Risperdal®'s side-effects; (4) Dr. Rebotira then conspired with Janssen for some unspecified reason; and (5) Dr. Rebotira prescribed Plaintiff Risperdal® as part of this ill-hatched scheme in violation of his oath to do no harm. The Court has no obligation to “accept as truth conflicting pleadings that make no sense . . . or by facts of which the court may take judicial notice.” *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 405-06 (S.D.N.Y. 2001); *see also Hirsch*, 72 F.3d at 1085.

Plaintiff provides no plausible allegations explaining how Janssen failed to provide warnings about Risperdal®'s side-effects to his physician(s). Indeed, the available evidence establishes that Janssen warned of liver damage and other side-effects on Risperdal®'s label *and* included this information in the PDR. And by Plaintiff's own admission, Dr. Rebotira knew about Risperdal®'s side-effects. These allegations are not sufficient to state a claim against Janssen. Accordingly, the Court should dismiss Plaintiff's failure-to-warn claim with prejudice.

C. Plaintiff Has Not Alleged that His Risperdal® Use Was Off-Label or that Any of His Purported Side-Effects Are Unique to Off-Label Use

As the Court explained to Plaintiff, should he seek to recover on this failure-to-warn theory for off-label Risperdal® use, he must “provide specific allegations explaining the purpose for which he has been prescribed Risperdal, the unique risks associated with his off-

label use, and why the warnings provided to his physicians were inadequate.” (March 30 Order, ECF No. 60 at 28.) Plaintiff has ignored these three directives.

First, Plaintiff has failed to identify the *specific* reason for which he was prescribed Risperdal® and it is unclear whether his use of the medication was, in fact, off-label. He alleges only that he was “diagnosed with depression and personality disorder.” (2d Am. Compl., ECF No. 61 at 4.) Plaintiff does not provide any additional information about these diagnoses—including any symptoms from which he suffered or whether his physician(s) indicated that Risperdal® was appropriate to treat those symptoms. Nor does Plaintiff identify the *specific* personality disorder with which he was diagnosed. His conclusory assertion that “the drug he was being administered by Defendants was never made to treat his diagnosis of personality disorder” does not remedy these deficiencies. (*Id.* at 8.)

Second, even assuming Plaintiff’s Risperdal® use was off-label—a fact that remains unclear—he fails to allege any unique health risks associated with that off-label use or any shortcomings with Risperdal®’s warnings. Indeed, Plaintiff does not allege any harm beyond liver damage. To illustrate, he alleges that “on Sept. 14, 2015 . . . it was discovered that Plaintiff was suffering from an enlarged liver and early stages of fatty liver disease.” (*Id.* at 4.) He alleges further that his psychiatrist and pharmacy “failed to warn Plaintiff of the possible side effects and risks that the drug in question could possibly contribute to his major organs, and in particular, his liver.” (*Id.* at 5.) And he claims that this alleged failure to warn “resulted in Plaintiff suffering liver disease.” (*Id.* at 7.)

Plaintiff makes no effort to allege that the liver damage from which he purportedly suffers is *uniquely* associated with Risperdal®’s use to treat depression and/or his unspecified “personality disorder.” Nor does he allege that Janssen should have included

warnings specific to liver damage beyond those already included in Risperdal®'s label. To the extent that Plaintiff mentions side-effects aside from liver damage, he does not allege that *he* suffers (or suffered) from those side-effects. Instead, he makes the conclusory assertions that ingredients purportedly used in Risperdal® have “been linked to nerve damage, as well as[] inflammatory bowel diseases.” (*Id.* at 8.) Ignoring the fact that this allegation appears to relate to an alleged design defect—a claim the Court has already dismissed—these allegations suggest only that *someone* may have developed these symptoms.

Third, Plaintiff again does not make any allegations regarding the *adequacy* of Risperdal®'s warnings for off-label use. Rather, as set forth in detail above, he ignores Risperdal®'s label in its entirety.

Plaintiff's failure to follow the Court's directive establishes that, to the extent he seeks to recover for alleged injuries purportedly resulting from off-label Risperdal® use, this claim should be dismissed with prejudice.

II. THE COURT SHOULD DENY PLAINTIFF FURTHER LEAVE TO AMEND

Janssen recognizes that courts should be more lenient when evaluating a *pro se* party's pleadings. But there are limits. A plaintiff's repeated failure “to cure the defects in his claims despite having received detailed instructions and despite the bases of the dismissals having been specified in advance” counsels against further leave to amend. *Payne v. Malemathew*, 2011 U.S. Dist. LEXIS 80649, at *19 (S.D.N.Y. July 22, 2011). That is precisely what has happened in this action.

Plaintiff has had three chances to state a claim against Janssen. Each round of briefing in this action—and each dismissal—has provided Plaintiff with a detailed description of why his pleadings are defective. As the Court itself has stated, “Plaintiff has already been

afforded an opportunity to amend the Complaint once. Despite such an opportunity, Plaintiff has failed to cure any deficiencies identified by the Court or Defendants. Instead, Plaintiff has only reasserted the same or similar conclusory allegations.” (March 30 Order, ECF No. 60 at 36 n.26.) The Second Amended Complaint is no different. The Court’s March 30 Order also provided Plaintiff with clear instructions explaining the allegations he was required to include in his Second Amended Complaint to survive dismissal. He did not follow them. His failure to do so establishes that he cannot cure the defects with his pleadings. Thus, any further amendments would be futile, *Terry v. Inc. Vill. of Patchogue*, 826 F.3d 631, 633 (2d Cir. 2016), and deprive Janssen of its right to a final disposition of this action, *see McKethan v. New York State Dep’t of Corr. Servs.*, 2012 U.S. Dist. LEXIS 84976, at *7 (S.D.N.Y. June 19, 2012). Accordingly, Plaintiff should not be permitted any further amendments.

CONCLUSION

For the foregoing reasons, Janssen Pharmaceuticals, Inc., and Janssen Research & Development, LLC respectfully request that the Court dismiss the Second Amended Complaint against them, with prejudice, pursuant to Fed. R. Civ. P. 12(b)(6) and that Plaintiff be denied any further leave to amend.

Dated: New York, New York
May 30, 2018

Respectfully submitted,
PATTERSON BELKNAP WEBB & TYLER LLP

By:  _____

John D. Winter

Thomas P. Kurland

1133 Avenue of the Americas

New York, NY 10036-6710

T: (212) 336-2000

E: jwinter@pbwt.com

tkurland@pbwt.com

*Attorneys for Defendants Janssen Pharmaceuticals,
Inc. and Janssen Research & Development, LLC*